

FIBROMYALGIA



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LEARNING OBJECTIVES

1. Demonstrate an understanding of the epidemiology of fibromyalgia, its impact on patient health, and the clinical controversy surrounding the syndrome.
2. Evaluate available treatment options and design a treatment plan for the patient with fibromyalgia.
3. Evaluate the available evidence regarding complementary and alternative medicine for fibromyalgia.
4. Justify the role of patient self-care in the treatment of fibromyalgia.
5. Construct a patient education strategy to aid patients in fibromyalgia self-management.

INTRODUCTION

Fibromyalgia is a syndrome characterized by chronic widespread pain. First described more than 100 years ago, the American College of Rheumatology (ACR) published official diagnostic guidelines in 1990. The first treatment guidelines were published 15 years later by the American Pain Society (APS). Since then, many controversies have surrounded both the diagnosis and management of fibromyalgia syndrome. Although the condition imposes

considerable patient impact, no medical specialty has yet claimed the disease. These patients are most often seen by rheumatologists. Fibromyalgia is often managed as part of primary care, and ambulatory care pharmacists can contribute an important role to its optimal management.

EPIDEMIOLOGY AND IMPACT

An estimated 2%–3% of Americans are affected by fibromyalgia, with a higher prevalence in women than men. The highest prevalence occurs between the ages of 60 and 79 years (Wolfe 1995). Patients may exhibit symptoms of fibromyalgia for 5 years before a diagnosis is made. A significant reduction in the quality of life may occur for patients with fibromyalgia. Fibromyalgia symptoms are worse and the quality of life is poorer for young (younger than 39 years) or middle-age (40–59 years) patients with fibromyalgia versus older (older than 60 years) patients (Jiao 2014).

In an Internet survey by the National Fibromyalgia Association, 1735 patients age 31–78 years reported being diagnosed with fibromyalgia; of those women, 25% reported difficulty with everyday tasks such as personal care and bathing (Jones 2008). More than 60% of those

BASELINE KNOWLEDGE STATEMENTS

Readers of this chapter are presumed to be familiar with the following:

- Pain pathways and mechanisms of treating neuropathic pain
- Basic pathophysiology and treatment of fibromyalgia
- Commonly used tools for assessment of pain and/or quality of life, such as the Medical Outcomes Study 36-Item Short-Form Health Survey and Brief Pain Inventory
- Use of motivational interviewing and other communication techniques

ADDITIONAL READINGS

The following free resources are available for readers wishing additional background information on this topic.

- Mayo Clinic. [Framework for Fibromyalgia Management for Primary Care Providers](#).
- Boomershine CS. [A comprehensive evaluation of standardized assessment tools in the diagnosis of fibromyalgia and in the assessment of fibromyalgia severity](#). Pain Res Treat 2012; 2012: 653714.

ABBREVIATIONS IN THIS CHAPTER

ACR	American College of Rheumatology
APS	American Pain Society
BPI	Brief Pain Inventory
CBT	Cognitive behavior therapy
FIQ	Fibromyalgia Impact Questionnaire
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SS	Symptom severity (scale)
WPI	Widespread Pain Index

diagnosed with fibromyalgia reported difficulty with light household tasks, walking up or down one flight of stairs, lifting or carrying 4.5 kg (10 lbs), and walking 0.5 miles; more than 90% reported difficulty with heavy household tasks, lifting or carrying 11.3 kg (25 lbs), and doing strenuous activities. On average, the women surveyed reported less functional ability in activities of daily living than the average community-dwelling woman in her 80s. Women with fibromyalgia report higher depression scores, greater perceived distress, and more frequent unsupportive relationships than women with a chronic (but medically recognized) autoimmune illness.

PATHOPHYSIOLOGY AND DIAGNOSIS

Chronic widespread pain is the hallmark symptom of fibromyalgia and has been proposed to be of neurogenic origin (Russell 2009). A central amplified pain perception is linked with allodynia and hyperalgesia. Fatigue and sleep disturbances are also common components of the syndrome. Other key symptoms include tenderness, mood disturbances, and cognitive difficulties. The cognitive impairment, manifested as a difficulty to concentrate and loss of memory, is often referred to as the *fibro fog*. All of these symptoms may fluctuate in intensity. Anxiety and other mood disorders are common comorbid conditions. Studies have shown the prevalence of lifetime anxiety disorder is 35% to 62% of patients with fibromyalgia, lifetime major depressive disorder in 58% to 86%, and lifetime bipolar disorder in 11% (Arnold 2006, Thieme 2004). Irritable bowel syndrome and tension headaches may also be comorbid conditions in patients with fibromyalgia. Survey results showed the 10 most common factors perceived by patients to worsen symptoms of fibromyalgia were: emotional distress, weather changes, sleeping problems, strenuous activity, mental stress, worrying, car travel, family conflicts, physical injuries, and physical inactivity (Bennett 2007).

Family history appears to be a risk factor for fibromyalgia, as does female sex. The latter factor is controversial because the incidence is similar between sexes when newer diagnostic criteria are used that do not include the

tender-point criteria. A strong genetic component has been suggested (Arnold 2013). Environmental factors such as physical trauma, infections, and stressors have been implicated as well (Mease 2005).

The diagnosis of fibromyalgia is made through clinical evaluation because, to date, no laboratory tests, radiographic studies, or biological markers have been established. Certain conditions (e.g., hypothyroidism, rheumatic diseases) can mimic the symptoms of fibromyalgia and should be assessed and excluded. Similarly, pain related to drug use (e.g., statin-induced myopathies, opioid-induced hyperalgesia) should be excluded.

The 1990 ACR diagnostic criteria were initially developed as research classification criteria and were not intended for use as a strict diagnostic tool in clinical practice. In an effort to differentiate fibromyalgia from other widespread pain, the concept of tender points was introduced (Wolfe 1990). Widespread pain of at least 3 months' duration and tenderness on pressure applied in at least 11 of 18 prespecified points on the body (termed *tender points*) were considered diagnostic for fibromyalgia, with sensitivity and specificity of 88% and 81%, respectively. Criticism centered around the finding that 19% of patients who had at least 11 tender spots did not truly have fibromyalgia and the concern that an individual with fibromyalgia pain that waxes and wanes does not meet the definition for chronic pain.

New diagnostic criteria for fibromyalgia were introduced in 2010 by the ACR and included 19 pain locations and 41 somatic symptoms (Wolfe 2010). These criteria were modified in 2011: most notably, the inclusion of tender points in the diagnosis was removed. Concerns regarding whether primary care providers were performing the tender point examination, as well as the accuracy of the examination as administered in primary care, led to removal of that criterion (Wolfe 2011). Instead, the focus became a symptom-based assessment. Symptoms are now evaluated using the widespread pain index (WPI) (Box 1-1) and the symptom severity (SS) scale (Box 1-2). These are combined for the proposed new definition of fibromyalgia: WPI of 7 or greater and SS score of 5 or greater; or WPI of 3–6 and SS of 9 or greater. The authors of the ACR criteria suggest that the SS scale may also be used to measure the current status of symptom severity once a diagnosis has been made. Although released in 2010, updated in 2011, and approved by the ACR Board of Directors, the ACR authors note that these criteria are still considered preliminary until external validation has been completed.

Compared with the original 1990 ACR criteria, the 2011 criteria provided 83% sensitivity, 67% specificity, and a correct classification of 74% (Bennett 2014). However, another set of diagnostic criteria has been developed since then and is used to assess pain location and symptom impact. For the 2013 alternative criteria, patients use a pain location inventory to note in which of the 28 specific

areas they have experienced pain in the past 7 days and complete a 10-item questionnaire regarding symptom impact (Bennett 2014). Evaluation of these criteria report sensitivity of 81%, specificity of 80%, and correct classification of 80% for fibromyalgia diagnosis.

The Fibromyalgia Diagnostic Screen has been developed specifically for use by primary care providers and combines clinical assessment with patient-reported data. This primary care screen includes mild pain in at least three of five classified body regions, duration of pain 3 months or longer, pain exacerbated by exercise or physical activity, and a SS score (Arnold 2012). The SS screen includes an abbreviated tender point examination. Five supplemental models have also been developed, some of which address confounding factors such as elevated erythrocyte sedimentation rate, thyroid-stimulating hormone levels, and joint swelling. Evaluation of this tool showed that it performed similarly to the 2010 modified ACR criteria but with greater sensitivity than the modified ACR criteria and with higher specificity than the Fibromyalgia Diagnostic Screen (Martin 2014). Further studies are warranted to evaluate the accuracy and value of this tool in primary care practice.

The Fibromyalgia Impact Questionnaire (FIQ) is a validated, 10-item instrument used to evaluate the impact of fibromyalgia on patient health and functional ability. Questions relate to physical function, pain level, fatigue, sleep disturbance, anxiety, and depression. Baseline scores can be obtained and then compared with subsequent scores after treatments are initiated. Many fibromyalgia studies use the FIQ as the primary or secondary outcome. Studies may also use the Brief Pain Inventory (BPI) or Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) as assessments of the syndrome's impact on patient well-being.

CLINICAL CONTROVERSY

Fibromyalgia is a common yet contested condition. Despite advances in research, fibromyalgia may be regarded as a default diagnosis rather than a distinct syndrome. Lack of laboratory criteria, uncertain clinical diagnostic tools, and the suggestion that the condition is “all in one's head” contribute to this discussion. Patients may feel stigmatized by the medical and nonmedical community alike, especially given that treatment centers on symptom relief rather than management of a disease process.

The release of the *Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5)* raised a new controversy with the identification of a new mental disease known as *somatic symptom disorder*. In short, this disorder could be diagnosed if a patient had at least one severe somatic symptom (e.g., limb or joint pain, headache) as well as one of the following: disproportionate and persistent thoughts about the seriousness of one's symptoms; persistently high level of anxiety about health or symptoms; or excessive

Box 1-1. Widespread Pain Index

Note the number of areas in which the patient has had pain over the last week.

Shoulder girdle, left
Shoulder girdle, right
Upper arm, left
Upper arm, right
Lower arm, left
Lower arm, right

Hip (buttock, trochanter), left
Hip (buttock, trochanter), right
Upper leg, left
Upper leg, right
Lower leg, left
Lower leg, right

Jaw, left
Jaw, right
Chest
Abdomen

Upper back
Lower back
Neck

Total Score (will be 0 to 19)

Box 1-2. Symptoms Severity Scale

Score is the sum of the severity of the three symptoms plus the extent (severity) of somatic symptoms in general. Score will be between 0 and 12.

Fatigue Waking Unrefreshed Cognitive Symptoms

For each of the 3 symptoms above, indicate the level of severity over the past week using the following scale:

0 = no problem

1 = slight or mild problems, generally mild or intermittent

2 = moderate, considerable problems, often present and/or at a moderate level

3 = severe: pervasive, continuous, life-disturbing problems

Considering somatic symptoms in general, indicate whether the patient has:

0 = no symptoms

1 = few symptoms

2 = a moderate number of symptoms

3 = a great number of symptoms

time and energy devoted to these symptoms or health concerns (APA 2013). Because many patients with fibromyalgia likely meet these criteria, concern arose that these patients would now receive the diagnosis of a mental disorder. Some clinicians think that the term *fibromyalgia* should be abandoned altogether in favor of alternative diagnosis as a somatic symptom disorder (Bass 2014).

PHARMACOTHERAPY

Several organizations have developed treatment guidelines for fibromyalgia, with notable heterogeneity in the recommendations. A comparison of the strongest recommendations from each guideline is presented in Table 1-1. Of note, the first drug to have a labeled indication for fibromyalgia gained the designation in June 2007. Both the APS and European League Against Rheumatism guidelines were developed before that time and therefore do not reflect these U.S. Food and Drug Administration (FDA) label approvals.

Drugs with FDA Label Approval for Fibromyalgia

Three drugs have a labeled indication for the treatment of fibromyalgia: pregabalin, duloxetine, and milnacipran.

Pregabalin

Pregabalin's effects on the release of excitatory neurotransmitters such as glutamate, norepinephrine, and substance P may contribute to pain reduction in patients with fibromyalgia. The manufacturer-recommended starting dosage is 75 mg twice daily, eventually titrated to 225 mg twice daily. Varying dose adjustments are required for patients with a CrCl less than 60 mL/minute.

A meta-analysis of three studies investigating the use of pregabalin for fibromyalgia found that patients taking pregabalin 300 mg, 450 mg, or 600 mg daily were significantly more likely to respond to treatment than patients taking placebo. The three randomized controlled trials included 1890 patients, and response was defined as a greater than 30% decrease in the main pain score from baseline.

Improvements in pain, measured by a numeric pain severity scale, were consistently demonstrated (for 600 mg, odds ratio [OR] 1.70, 95% confidence interval [CI], 1.27–2.29; for 450 mg, OR 1.92, CI, 1.49–2.48; for 300 mg, OR 1.53, CI, 1.18–1.98). Conflicting results were shown in regard to improvements in fatigue and various scales for symptom severity. Treatment with pregabalin caused significantly more dizziness, somnolence, dry mouth, weight gain, and peripheral edema than placebo, especially for the patients taking 600 mg daily (Tzellos 2010).

A comparison between traditional twice-daily dosing and once-nightly dosing of pregabalin in 177 patients with fibromyalgia for a mean duration of around 4 years showed no significant differences. Both dosing strategies significantly reduced pain as measured by a standard 0–10 rating scale and caused similar rates of adverse effects. Simply from a convenience standpoint, once-nightly dosing of pregabalin may be preferable, although adherence rates in the study were similar (Nasser 2014).

Duloxetine and Milnacipran

The exact mechanism is unknown, but it is theorized that duloxetine and milnacipran may improve fibromyalgia symptoms through their analgesic properties, which result from effects on descending inhibitory pathways. Benefits may also occur because of their efficacy in improving the anxiety and depression that commonly accompanies fibromyalgia pain. For both agents, dosages that improve fibromyalgia symptoms are generally lower than those needed to provide antidepressant efficacy. In vitro milnacipran is slightly more

Table 1-1. Comparison of Strong Recommendations from Guidelines

American Pain Society (2005)	European League Against Rheumatism (2008)	German (2012)	Canadian (2013)
Tricyclic antidepressants: amitriptyline	Tramadol	Aerobic exercise	Tricyclic antidepressants
Cyclobenzaprine	Antidepressants: amitriptyline, fluoxetine,	Cognitive behavior therapy	Serotonin norepinephrine reuptake inhibitors
Aerobic exercise	duloxetine, milnacipran	Antidepressants	Selective serotonin reuptake inhibitors
Cognitive behavior therapy	Pregabalin or pramipexole	Multicomponent therapy	Anticonvulsants
Multicomponent therapy			Cognitive behavior therapy
			Multimodal approach to treatment
			Interventions that improve self-efficacy
			Graduated exercise program

Information from: Burckhardt CS, Goldberg D, Crofford L et al. [Guideline for the management of fibromyalgia syndrome pain in adults and children](#). APS Clinical Practice Guideline Series, No 4, 2005; Carville SF, Arendt-Nielsen S, Bliddal H, et al. EULAR evidence based recommendations for the management of fibromyalgia syndrome. *Ann Rheum Dis* 2008;67:536-541; Winkelmann A, Häuser W, Friedel E, et al. [Physiotherapy and physical therapies for fibromyalgia syndrome. systematic review, meta-analysis and guideline](#). *Schmerz* 2012;26:276-86; and Fitzcharles MA, Ste-Marie PA, Goldenberg DL, et al. [2012 Canadian guidelines for the diagnosis and management of fibromyalgia syndrome: executive summary](#). *Pain Research&Management* 2013;18:119-26.

noradrenergic than duloxetine and therefore might show more benefits for fatigue and memory problems, although this hypothesis has not been proven clinically.

According to manufacturer recommendations, milnacipran should be started at a dosage of 12.5 mg once daily and titrated up to 50 mg twice daily. Dosage adjustments are needed for patients with severe kidney impairment (CrCl 5–29 mL/minute). In a 15-week randomized double-blind trial comparing milnacipran with placebo, milnacipran demonstrated significant improvements in the Patient's Global Impression of Change scale, physical function, and fatigue (Clauw 2008). A 6-month trial showed that milnacipran was more likely to reduce pain and fatigue than placebo (Mease 2009). Milnacipran may cause increased blood pressure or heart rate, nausea, hot sweats and/or diaphoresis, and headache. Sustained effects of milnacipran were evaluated in an open-label, flexible-dosing study. Tolerability and symptom improvements in terms of pain score and SF-36 physical component score were maintained over the study duration of up to 3.25 years (Arnold 2013).

The recommended starting dosage of duloxetine for fibromyalgia is 30 mg once daily, titrated after 1 week to 60 mg once daily. Use of duloxetine is not recommended for patients with CrCl less than 30 mL/minute. In a study of duloxetine versus placebo for fibromyalgia, statistically significant improvements were seen in BPI and Patient's Global Impression of Change scale scores with duloxetine (Russell 2008). A similar trial noted improvements in FIQ and BPI scores, as well as a decreased number of tender points and an increased quality of life (Arnold 2004). Adverse effects of duloxetine include dry mouth, fatigue and somnolence, nausea, constipation, and headache.

Direct Comparisons

No direct clinical comparisons between pregabalin, duloxetine, and milnacipran for fibromyalgia have been conducted. A systematic review compared their efficacy using studies published on each drug individually. In general, all drugs were superior to placebo. Duloxetine was similar to placebo for fatigue, similar to milnacipran for sleep disturbances, and similar to pregabalin for depressed mood (Hauser 2010). Symptom reduction differed among the drugs, with duloxetine and pregabalin superior to milnacipran for pain reduction and improvements in sleep disturbance; duloxetine superior to pregabalin and milnacipran for reducing depressed mood, and duloxetine inferior to milnacipran and pregabalin for fatigue. Adverse effect profiles were similar, although headache and nausea were more common with duloxetine and milnacipran than pregabalin.

Off-label Drug Therapies

Tricyclic Antidepressants

Tricyclic antidepressants have long been the mainstay of fibromyalgia treatment. Their low cost and benefit in

chronic neuropathic pain has supported the use of this class. Amitriptyline is recommended by all treatment guidelines shown in Table 1-1. A systematic review of 10 randomized controlled trials evaluated amitriptyline, at dosages of 25 or 50 mg daily, in 615 patients (Nishishinya 2008). Six of the 10 trials used 25 mg daily, which significantly improved pain, sleep disturbances, and fatigue, and both patient and physician global assessments. Amitriptyline 50 mg daily did not show a benefit over placebo, possibly because of a large adverse event-related drop out rate. As expected, adverse effects included dry mouth, somnolence, gastrointestinal disturbances, and weight gain. No dosage adjustments are required for impaired kidney function.

Cyclobenzaprine

Structurally similar to tricyclic antidepressants, cyclobenzaprine has been studied for the treatment of fibromyalgia. Five trials were included in a meta-analysis comparing cyclobenzaprine, at dosages of 10–30 mg daily, with placebo. Sleep and pain symptoms improved for three times the number of patients taking cyclobenzaprine versus placebo (Tofferi 2004). Fatigue or tender points did not improve with cyclobenzaprine, and 85% of the patients taking cyclobenzaprine reported adverse effects. The first treatment guidelines for fibromyalgia published by the APS in 2005 included cyclobenzaprine with a strong recommendation supporting its use.

Gabapentin

Data are limited regarding the role of gabapentin in the treatment of fibromyalgia. Although not extensively studied, gabapentin's similarity to pregabalin suggests a potential benefit. Compared with placebo, gabapentin titrated to a dosage of 1200–2400 mg/day significantly improved the pain severity score as measured by BPI Short Form and showed significant difference in response rates (Arnold 2007). Other scales for symptom severity, including an assessment of sleep, showed benefits with gabapentin compared with placebo. Dizziness, weight gain, and sedation were noted with gabapentin.

Venlafaxine

Two small open-label studies with venlafaxine have been conducted, one using immediate release venlafaxine 37.5–375 mg daily in 15 patients and one using venlafaxine 75 mg daily in 20 patients. In both trials, pain improved from baseline using a visual scale and pain questionnaire (Dwight 1993, Sayar 2003). More data are needed to recommend venlafaxine as an alternative to duloxetine or milnacipran for fibromyalgia.

Selective Serotonin Reuptake Inhibitors

Fluoxetine, paroxetine, and citalopram have been studied for the treatment of fibromyalgia. In general, they are better tolerated than tricyclic antidepressants, especially

for those experiencing anticholinergic adverse effects, but these drugs have less efficacy for fibromyalgia symptoms (Sarzi-Puttini 2008).

Dopamine Agonists

Dopamine agonists may decrease adrenergic arousal that may contribute to disordered sleep in patients with fibromyalgia. Pramipexole and ropinirole have been studied for the treatment of fibromyalgia. In a small 14-week trial of 60 patients initiated on treatment with pramipexole, 42% of patients had a 50% or more reduction in their pain score using a visual analog scale, compared with 14% of patients taking placebo (Holman 2005). A trial of ropinirole found no benefit; however, the discontinuation rate was high (63%) for both intolerance and lack of efficacy (Holman 2003).

Pain Medications

Although pain is a characteristic feature of fibromyalgia, analgesics are often of limited clinical value.

Tramadol

For those patients who can tolerate its adverse effects, tramadol may be beneficial in reducing the severity of pain associated with fibromyalgia. A trial of tramadol in the treatment of fibromyalgia pain found that 69% of the 100 patients were able to tolerate the drug in an open-label run-in phase (Russell 2000). Of those 69 patients, 35 were randomized to tramadol in the double-blind placebo-controlled phase. Compared with placebo, the patients receiving tramadol showed statistically significant improvements in pain intensity, pain relief, and myalgic scores. A careful consideration of adverse effects and the abuse potential should be considered before tramadol is used for fibromyalgia pain relief.

Opioids

Opioids are not recommended for fibromyalgia because these drugs may actually worsen symptoms such as fatigue and cognitive impairment. A 1-year observational study evaluated the use of opioids in 1700 adults with fibromyalgia and found that patients taking nonopioid pain relievers demonstrated greater improvements in assessments such as the BPI and FIQ (Peng 2014).

Other Pain Medications

Nonsteroidal anti-inflammatory drugs and acetaminophen act peripherally and are therefore less likely to be of benefit for the centrally mediated pain mechanisms that are associated with fibromyalgia.

Potential Future Pharmacotherapy Options

Most trials have used the 1990 ACR criteria as the basis for diagnosis of fibromyalgia. The newer criteria as modified in 2011 may capture more patients with fibromyalgia than the original 1990 criteria. New studies may

use updated criteria, making direct comparisons between studies and patient populations difficult. A search in the clinical trials database available at clinicaltrials.gov revealed many ongoing studies investigating treatment options for fibromyalgia, such as extended-release cyclobenzaprine, cannabinoids, neurotrophin, etoricoxib, memantine, naltrexone, and lidocaine.

BEYOND PHARMACOTHERAPY

Given the modest benefits of most drugs, many patients may use nonpharmacologic approaches. Survey reporting showed 91% of patients with fibromyalgia were using nonpharmacologic therapies to manage symptoms, with two-thirds using more than one complimentary therapy (Piro-Boisset 1996).

Nonpharmacologic Therapy

Cognitive Behavior Therapy

Cognitive behavior therapy (CBT) is the combination of cognitive therapy to modify maladaptive thoughts with behavioral therapy to increase adaptive behavior. This therapy is often employed as a treatment for depression and anxiety. Its role in fibromyalgia management has been suggested as an adjunct to drug therapy. Several randomized controlled trials of 6 to 30 months in duration found that CBT improved function and decreased the severity of pain in fibromyalgia (Creamer 2000, Hadhazy 2000, Nielson 1992, Singh 1998, White 1995). Two systematic reviews showed improved pain, mood, fatigue, and function when CBT was used for fibromyalgia treatment (Rossy 1999, Williams 2003).

A meta-analysis of mindfulness-based stress reduction used in chronic pain and stress disorders for fibromyalgia showed minimal benefit (Lauche 2013). This finding suggests that behavioral therapy alone is insufficient and further supports the use of the combined therapy offered in CBT.

Exercise

Exercise as a therapy for fibromyalgia may appear paradoxical given the syndrome's classic symptoms of pain and fatigue. However, strong evidence supports exercise as an effective treatment. Aerobic exercise is most often recommended, but resistance and flexibility exercise may also be of benefit. A review of 16 trials that focused on exercise as a treatment for fibromyalgia divided exercise interventions into categories of single exercise (aerobic training, strength training, flexibility training) or more than one type of exercise (mixed training). Benefits were noted in all exercise groups compared with control groups with regard to aerobic performance, tender-point pain pressure threshold, and pain (Busch 2002). A review that focused specifically on resistance training showed improvements in overall well-being, physical function, pain reporting, tenderness, and muscle strength, thereby supporting a role for resistance training in fibromyalgia treatment (Busch 2013).

In one study, intervention with motivational interviewing added to an exercise program improved outcomes, notably improvements in FIQ scores and 6-minute walk test results, compared with exercise plus standard self-management lessons (Ang 2013). Lifestyle physical activity is often recommended and may be more appealing than a structured exercise program to many patients with fibromyalgia. However, compared with standard education and support, a lifestyle intervention integrating short bouts of activity into the day by increasing walking or using the stairs did not show sustained benefit (Fontaine 2011); therefore a structured exercise program is recommended. Patients should be counseled to seek professional help when attempting an exercise program for fibromyalgia in order to avoid injury.

Vitamin D

Evidence is conflicting regarding the role of vitamin D in the pathophysiology of fibromyalgia. In one study, patients with fibromyalgia and vitamin D deficiency, defined as a vitamin D level less than 32 ng/mL, were randomized to cholecalciferol or placebo. Cholecalciferol dosages were adjusted to achieve a target serum calcifediol concentration of 32 to 48 ng/mL. Reductions in pain and improvements in the SF-36 score occurred in patients who had achieved the target values (Wepner 2014). Given the small study size and lack of supporting studies, more evidence is needed to routinely recommend vitamin D supplementation for fibromyalgia.

Complementary Medicine

Tai Chi

Originally a Chinese martial art, tai chi is a mind-body practice that combines meditation, slow movements, and deep breathing. It is thought to move energy throughout the body. In a randomized single-blind study comparing classic tai chi with control (wellness education and stretching exercises), tai chi showed greater benefit with regards to FIQ scores, SF-36 physical-component scores, and SF-36 mental-component scores (Wang 2010). Benefits seen at 12 weeks were sustained at 24 weeks. Tai chi adapted as pool-based therapy—with the thought that the warm pool water and increased buoyancy would help minimize pain—also showed significant improvement in the FIQ scores that was not seen in pool-based stretching (Calandre 2009). Significant improvements were also seen in Pittsburgh Sleep Quality Index scores in those who participated in pool-based tai chi but not for those doing stretching exercises in the pool.

Acupuncture

Acupuncture, defined as the stimulation of specific points of skin on the body using heat, pressure, laser, or small needles, has been suggested as a complementary treatment for fibromyalgia, although efficacy data are lacking. A review of nine trials concluded acupuncture had no better effect for pain relief than sham acupuncture, suggesting a placebo effect (Deare 2013). A broadened review of 16 trials

of acupoint stimulation including acupuncture, cupping therapy, moxibustion, point injection, point embedding, or a combination had similar findings (Cao 2013).

Other Complementary Modalities

Music has been suggested to help provide an analgesic effect and improve functional mobility measured by the “timed-up and go task” in patients with fibromyalgia (Garza-Villarreal 2014). Evidence also suggests that hydrotherapy may be of benefit for the treatment of fibromyalgia in regards to pain, health status, and tender point count (McVeigh 2008). A review of nine randomized controlled trials found patients with fibromyalgia had significant improvements in pain, anxiety, and depression after massage therapy treatment (Li 2014). Manual therapy, which includes massage therapy and joint (spinal and extremity) manipulation or mobilization, has been shown to be beneficial for fibromyalgia symptoms, but with sex differences in response. Manual therapy improved quality of sleep and tender point count in men and women, although women showed a greater reduction in pain and perceived impact of fibromyalgia symptoms and men showed greater decreases in pressure hypersensitivity and depressive symptoms (Castro-Sanchez 2013).

PATIENT EDUCATION AND RESOURCES

Education provided to patients about the chronic and waxing/waning nature of fibromyalgia symptoms has been shown to lead to fewer symptoms reported and decreased symptom intensity (Huynh 2008). Therefore patient education plays a vital role in fibromyalgia management. Survey reporting showed the most common interventions used by responders for their fibromyalgia were rest, distraction, heat modalities, nutritional supplements, nonprescription and prescription analgesics, gentle walking, prescription antidepressants, stretching, and prayer (Bennett 2007). Interventions with more supporting evidence, such as aerobic and/or resistance exercise, cognitive behavior therapy, and tai chi were not listed by patients on the survey. Patients should be educated on the potential benefits of these treatment options and encouraged to try them. Patients should also be encouraged to identify stressors that worsen symptoms and to try approaches to lessen these stressors. Counseling on proper sleep hygiene can assist patients with improving sleep-related symptoms. The [National Fibromyalgia Association](#) offers many free resources for patients, including online support forums, a digital magazine, and information about local support groups.

CONCLUSION

Despite developments in research, fibromyalgia remains a challenging condition for many clinicians and patients. Understanding of the nuances between treatment options

is the key to proper patient care. Nonpharmacologic treatments may improve symptoms. The choice of treatment should be patient-specific and should be focused on symptom relief. Patient education and self-care are equally as important as pharmacotherapy when treating fibromyalgia symptoms. The ambulatory care pharmacist can play an integral role in managing fibromyalgia.

Practice Points

In determining the optimal pharmacotherapy for the treatment of fibromyalgia, practitioners should consider the following:

- Treatment should be chosen based upon the patient's most bothersome symptom(s) and the adverse effect profiles of available drug options.
- Nonpharmacologic and complementary treatments should be encouraged when appropriate.
- A multimodal treatment approach is recommended.
- Patients should be involved in treatment making decisions.
- Patient education is an important component of fibromyalgia treatment.
- The ambulatory care pharmacist can use motivational interviewing techniques to assist patients with self-treatment.

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SELF-ASSESSMENT QUESTIONS

1. A 49-year-old man with fibromyalgia has been treated with pregabalin 225 mg twice daily for 4 weeks. The patient is pleased with how his symptoms of pain have improved. His fatigue has also improved, but only marginally. Which one of the following is best to recommend for this patient?
 - A. Increase pregabalin to 600 mg daily.
 - B. Change to duloxetine 30 mg daily.
 - C. Continue pregabalin 450 mg daily.
 - D. Change to milnacipran 12.5 mg daily.
2. A patient with fibromyalgia has a medical history of stage IV chronic kidney disease. Which of the following would be safest to use at standard recommended doses to manage this patient's fibromyalgia?
 - A. Amitriptyline.
 - B. Duloxetine.
 - C. Milnacipran.
 - D. Pregabalin.
3. A patient with fibromyalgia complains of decreased sleep quality as her most bothersome symptom. She does not want to use duloxetine, milnacipran, or pregabalin based on the boxed warnings with each drug. Which one of the following is best to recommend for this patient?
 - A. Acupuncture.
 - B. Tai chi.
 - C. Amitriptyline.
 - D. Pramipexole.

Questions 4 and 5 pertain to the following case.

As the lead pharmacist in the AllFam family medicine clinic, you and your team plan to offer educational sessions for patients who are receiving a drug for fibromyalgia.

4. Which one of the following best justifies establishing this new service in the AllFam clinic?
 - A. Education is recommended as part of a treatment regimen for fibromyalgia.
 - B. Education will ensure the patient's safe use of the drug.
 - C. Education added to drugs has been shown to reduce symptoms and symptom intensity.
 - D. Education may increase adherence to drugs.
5. One year later, the AllFam clinic pharmacists have educated 35 patients with fibromyalgia. Of these patients, 60% noted significant improvements in their Fibromyalgia Impact Questionnaire score, compared

with 20% of the 35 matched controls who did not receive education. Which one of the following best describes the number needed to treat for this new service?

- A. 2
- B. 4
- C. 7
- D. 10

Questions 6 and 7 pertain to the following case.

J.A. is a 51-year-old woman with a new diagnosis of fibromyalgia after 2 years of unexplained pain, sadness, and fatigue. J.A. is discouraged with her situation, stating "I guess I'm just going to have to get used to the fact I will be in pain for the rest of my time on earth" and "I feel this has taken over my life." Her medical history includes hypertension, which is controlled by lisinopril 20 mg/hydrochlorothiazide 25 mg daily, and menopausal vasomotor symptoms.

6. Which one of the following is best to recommend for J.A.?
 - A. Duloxetine.
 - B. Sertraline.
 - C. Milnacipran.
 - D. Pregabalin.
7. Which one of the following nonpharmacologic treatments would be best to recommend for J.A.?
 - A. Tai chi.
 - B. Massage therapy.
 - C. Aerobic and resistance exercise.
 - D. Cognitive behavior therapy.
8. A 38-year-old woman who received a diagnosis of fibromyalgia 1 year ago presents to your clinic. Her pain related to her fibromyalgia is well controlled on hydrocodone 10 mg/acetaminophen 325 mg 1 tablet every 6 hours. However, she has increasing concern with her cognitive abilities and thinks she has "fibro fog," which she read about online. Which one of the following is best to recommend for this patient?
 - A. Discontinue hydrocodone/acetaminophen.
 - B. Discontinue hydrocodone/acetaminophen and start milnacipran.
 - C. Discontinue hydrocodone/acetaminophen and start duloxetine.
 - D. Add either duloxetine or milnacipran.

9. A 45-year-old woman presents to the clinic with complaints of fatigue, overall aches and pains, and constipation. Which of the following laboratory tests would be best to obtain for this patient before making a diagnosis of fibromyalgia?
- Thyroid-stimulating hormone (TSH).
 - Erythrocyte sedimentation rate (ESR).
 - TSH and vitamin D.
 - TSH, ESR, and vitamin D.
10. Which of the following is most consistent with criticism surrounding the use of “tender points” in the diagnosis of fibromyalgia?
- It may mask the true incidence of fibromyalgia in men.
 - It does not capture that the pain is widespread.
 - It takes a specially-trained clinician to administer the examination.
 - Patients may falsely report tender points to obtain medication.
11. A patient with fibromyalgia has her pain symptoms well controlled on pregabalin and reports minimal adverse effects. The patient is switching jobs and will be without insurance coverage for 6 months. Which one of the following is best to recommend for this patient?
- Change to gabapentin.
 - Discontinue pregabalin until insurance benefits return.
 - Replace pregabalin with cognitive behavior therapy.
 - Continue pregabalin.
12. For which one of the following patients would amitriptyline be preferred over milnacipran?
- A 37-year-old woman with a high insurance deductible.
 - A 66-year-old man with glaucoma.
 - A 75-year-old woman with orthostatic hypotension.
 - A 41-year-old man with altered sleep pattern because of shift work.
13. A patient with newly diagnosed fibromyalgia inquires about complementary and alternative medicine (CAM) after researching fibromyalgia on the Internet. What would be the most appropriate response to the patient regarding CAM?
- There is not enough evidence to suggest CAM is beneficial for fibromyalgia.
 - All CAM options provide the same results, which are not much better than placebo.
 - The patient should avoid CAM in favor of more efficacious drug treatment options.
 - Encourage a trial of CAM for relief of symptoms, either in addition to or in place of drug treatment options.
14. A patient inquires about the use of vitamin D to treat her fibromyalgia symptoms, stating that she read about its potential benefit online and has just started taking an over-the-counter supplement. What is best to recommend to this patient?
- She should discontinue vitamin D until she discusses with her physician.
 - Vitamin D supplements should be tried by everyone with fibromyalgia for symptom management.
 - Supplemental vitamin D may provide symptom relief if she is deficient, but first she should have a blood test to determine her current vitamin D levels.
 - There is not enough evidence to say whether or not she should take vitamin D supplements.

Questions 15–17 pertain to the following case.

P.T. is a 47-year-old woman new to your clinic. She presents with complaints of sleep disturbances, fatigue, and pain; she feels these symptoms are affecting her overall quality of life. She states the sleep disturbances cause her to feel unrested even after a full night’s sleep, and she is fatigued throughout the day on most days of the week. P.T. has greatly increased her caffeine intake to make up for this. She has not noticed cognitive symptoms related to her lack of sleep. In regards to the pain, she says it is most noticeable in her entire arms, hips, upper legs, and upper and lower back. Most days of the week she also notices gastrointestinal symptoms as well. This has been ongoing for about 6 months. The resident physician performs a tender point examination on P.T. and finds 12 tender points present

15. Which one of the following best describes P.T.’s score on the Widespread Pain Index?
- 4
 - 5
 - 6
 - 10
16. Which one of the following best describes P.T.’s score on the Symptom Severity Scale?
- 5
 - 6
 - 7
 - 8

17. Based upon available diagnostic criteria for fibromyalgia, which one of the following criteria is P.T. most likely to satisfy?
- A. 1990 ACR Criteria.
 - B. 2011 Modified ACR Criteria.
 - C. Both 1990 and 2011 ACR Criteria.
 - D. Neither 1990 nor 2011 ACR Criteria.
18. You have just completed motivational interviewing training and decide to try this communication technique with a patient with fibromyalgia. Which of the following statements would be most appropriate in a dialogue promoting patient self-care?
- A. "Why do you think I'm suggesting you start exercising?"
 - B. "Do you mind if I share some information with you about the benefits of exercise for fibromyalgia?"
 - C. "Don't you want to improve your symptoms?"
 - D. "Why are you so against taking care of yourself?"
19. A 57-year-old woman was diagnosed with fibromyalgia about 5 years ago. For the past 2 years her fibromyalgia symptoms have been well controlled with pregabalin 300 mg daily and a regular exercise program. In the past 3 months she has had to deal with several life stressors and now feels her fibromyalgia symptoms (namely pain and cognitive symptoms) have worsened. Which one of the following is most likely to improve her symptoms?
- A. Increase pregabalin to 450 mg daily.
 - B. Change to duloxetine 30 mg.
 - C. Cognitive behavior therapy.
 - D. Tai chi.
20. Which one of the following patients with fibromyalgia is most likely to benefit from milnacipran?
- A. A 38-year-old man with a new diagnosis of fibromyalgia and a primary complaint of sleep disturbances.
 - B. A 47-year-old woman who had fatigue symptom relief from duloxetine but could not tolerate the drug's adverse effects.
 - C. A 51-year-old woman being treated with amitriptyline but still experiencing pain.
 - D. A 44-year-old man who has most of his symptoms relieved through exercise but complains of depressed mood.

LEARNER CHAPTER EVALUATION: FIBROMYALGIA.

As you take the posttest for this chapter, also evaluate the material's quality and usefulness, as well as the achievement of learning objectives. Rate each item using this 5-point scale:

- Strongly agree
 - Agree
 - Neutral
 - Disagree
 - Strongly disagree
1. The content of the chapter met my educational needs.
 2. The content of the chapter satisfied my expectations.
 3. The author presented the chapter content effectively.
 4. The content of the chapter was relevant to my practice and presented at the appropriate depth and scope.
 5. The content of the chapter was objective and balanced.
 6. The content of the chapter is free of bias, promotion, or advertisement of commercial products.
 7. The content of the chapter was useful to me.
 8. The teaching and learning methods used in the chapter were effective.
 9. The active learning methods used in the chapter were effective.
 10. The learning assessment activities used in the chapter were effective.
 11. The chapter was effective overall.

Use the 5-point scale to indicate whether this chapter prepared you to accomplish the following learning objectives:

12. Demonstrate an understanding of the epidemiology of fibromyalgia, its impact on patient health, and the clinical controversy surrounding the syndrome.
13. Evaluate available treatment options and design a treatment plan for the patient with fibromyalgia.
14. Evaluate the available evidence regarding complementary and alternative medicine for fibromyalgia.
15. Justify the role of patient self-care in the treatment of fibromyalgia.
16. Construct a patient education strategy to aid patients in fibromyalgia self-management.
17. Please provide any specific comments related to any perceptions of bias, promotion, or advertisement of commercial products.
18. Please expand on any of your above responses, and/or provide any additional comments regarding this chapter: